K02035/

FEB 2 6 2002

510(k) SUMMARY

SUBMITTER: Dideco S.p.A.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON: Luigi Vecchi
Phone: 011 39 0535 29811
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DATE PREPARED: February 21, 2002

DEVICE TRADE NAME: D 903 AVANT 2 Ph.I.S.I.O (Phospholipidic Inert Surface In Oxygenation) Adult Hollow Fiber Oxygenator

COMMON NAME: Hollow Fiber Oxygenator/Reservoir

CLASSIFICATION NAME: Cardiopulmonary Bypass Oxygenator

PREDICATE DEVICES:

Dideco D 903 AVANT Adult Hollow Fiber Oxygenator (K980600)

D 901 Lilliput Ph.I.S.I.O. Infant Hollow Fiber Oxygenator (K010478)

Monolyth Mimesys Hollow Fiber Oxygenator (K004001)

DEVICE DESCRIPTION:

The D 903 AVANT Ph.I.S.I.O is a hollow fiber membrane oxygenator with integral heat exchanger and a hardshell cardiotomy venous reservoir.

INDICATION FOR USE:

The D 903 AVANT Ph.I.S.I.O. Adult Hollow Fiber Oxygenator with Integral Hardshell Venous Reservoir is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:

The D 903 AVANT Ph.I.S.I.O. hollow fiber oxygenator is identical in design, operating principles and control mechanisms to the D 903 AVANT adult hollow fiber oxygenator predicate device. The only modification made to the device is the biocompatible phosphorylcholine coating treatment added to all blood contact surfaces. The coating is identical to the phosphorylcholine coating used on the D 901 Lilliput Ph.I.S.I.O. and Monolyth Mimesys predicate devices.

The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the D 903 AVANT Ph.I.S.I.O. The device was aged up to 2 years and was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

IN VITRO TEST RESULTS:

In vitro testing were carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) submissions – Final Guidance for Industry and FDA Staff" issued on November 13, 2000 and when applicable, following the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. The device was aged up to 2 years and was tested for gas transfer characteristics, pressure drop, plasma leakage data, operating blood volume, heat exchanger performance evaluation, hemolysis/cell depletion, mechanical integrity, and leaking/flaking test. The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the D 903 AVANT predicate device.

The results of the study showed the device characteristics between D 903 AVANT Ph.I.S.I.O. and D 903 AVANT were comparable.

MARKETING HISTORY:

Currently the Dideco D 903 AVANT Adult Hollow Fiber Oxygenator is in commercial distribution in Europe since 1999 and currently about 8800 units have been sold. No reports of adverse events involving patient safety due to malfunctioning have been received.

CONCLUSIONS:

The results of *in vitro* gas transfer studies demonstrate that the D 903 AVANT Ph.I.S.I.O. Adult Hollow Fiber Membrane Oxygenator performs in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible, and functional tests demonstrate that the D 903 AVANT Ph.I.S.I.O. is equivalent to the predicate device, according to its intended use. Additional testing has demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 6 2002

Mr. Barry Sall, RAC
Senior Regulatory Consultant
DIDECO S.P.A.
c/o Parexel International Corporation
195 West Street
Waltham, MA 02451-1163

Re: K020351
Trade Name: D903 AVANT 2 Ph.I.S.I.O. Hollow Fiber Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator.
Regulatory Class: Class II (two)
Product Code: DTZ
Dated: February 1, 2002
Received: February 4, 2002

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020351

Device Name: Dideco D 903 Avant 2 Adult Hollow Fiber Oxygenator with Ph.I.S.I.O. coating

Indications For Use:

The Dideco D 903 Avant 2 Ph.I.S.I.O. Adult Hollow Fiber Oxygenator with Integral Hardshell Venous Reservoir is intended for use in adults who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The venous reservoir with cardiotomy filter is intended to collect blood aspirated from the operating field during surgical procedures and the blood from patient's veins during normal operation to assure the proper oxygenation capability of the device. The device is intended to be used for six hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020351

Prescription Use ✓ OR Over-The-Counter Use __
(Per 21 CFR 801.109)